

June 24, 1999

MEMORANDUM

SUBJECT: Trichlorfon (057901); List A Reregistration Case No. 0104; Product and Residue Chemistry Chapters For The Reregistration Eligibility Document (RED).
DP Barcode D257225.

FROM: Thurston G. Morton, Chemist
Reregistration Branch 4
Health Effects Division (7509C)

THRU: Susan V. Hummel, Senior Scientist
Reregistration Branch 4
Health Effects Division (7509C)

TO: Carmelita White/ Betty Shackleford, PM #53
Reregistration Section
Special Review and Reregistration Division (7508W)

Attached are the updated Trichlorfon Product and Residue Chemistry Chapters for the Trichlorfon RED. The initial chapters were completed by Dynamac Corporation under the supervision of HED. They have undergone secondary review (S. Hummel, D199005) and have been revised to reflect HED policies.

No registrations exist for use of trichlorfon on food crops. Registrations exist for use of trichlorfon as a direct pour-on treatment to cattle. Some non-food uses remain. Product and residue chemistry data are needed to support the dermal pour-on uses.

cc : Chem F, Chron F. Morton

RDI:Team: 6/22/99; SVH:6/24/99

TM, Thurston Morton, Rm. 816D CM2, 305-6691, mail code 7509C

TRICHLORFON

REREGISTRATION ELIGIBILITY DOCUMENT:

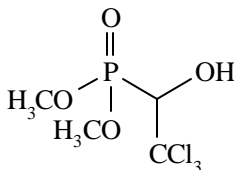
PRODUCT CHEMISTRY CONSIDERATIONS

PC Code: 057901; Case No. 0104

(DP Barcode D257225)

DESCRIPTION OF CHEMICAL

Trichlorfon [dimethyl (2,2,2-trichloro-1-hydroxyethyl) phosphonate] is an organophosphorus insecticide used on various sites including dermal pour-on for cattle for import purposes.



Empirical Formula:	C ₄ H ₈ O ₄ Cl ₃ P
Molecular Weight:	257.6
CAS Registry No.:	52-68-6
PC Code :	057901

IDENTIFICATION OF ACTIVE INGREDIENT

Technical trichlorfon is a white crystalline solid with a melting point of 75-84 C. Trichlorfon is soluble in water, dichloromethane, 2-propanol, and toluene, and nearly insoluble in n-hexane.

MANUFACTURING-USE PRODUCTS

A search of the Reference Files System (REFS) conducted 6/7/99 identified the following trichlorfon manufacturing-use products (MPs) registered under PC Code 057901 to Bayer Corporation: a 98% technical product (T; EPA Reg. No. 3125-9), and an 80% formulation intermediate (FI; EPA Reg. No. 3125-371). These products are the only MPs subject to a reregistration eligibility decision.

REGULATORY BACKGROUND

The regulatory background for trichlorfon products in terms of comprehensive product chemistry reviews is presented in Table 1. In summary, the Trichlorfon Guidance Document dated 6/84 required data for all product chemistry topics in support of the reregistration of trichlorfon. The Trichlorfon Reregistration Standard Update dated 5/15/90 and its Addendum dated 7/23/90 summarized all product chemistry data submitted since the Reregistration Standard. The Addendum reiterated the conclusions of the Update and included/reviewed data submitted for products registered subsequent to issuance of the Guidance Document, which, consequently, had been omitted from the Update.

Table 1. Regulatory background for trichlorfon MPs.

Products (EPA Reg. No.)	June 1984 Guidance Document		May 1990 Update and/or July 1990 Update Addendum	
	Data Required	Data submitted in response	Data required	Data submitted in response
98% T (3125-9)	61-1, -2, -3 62-1, -2, -3 63-2 through -20	61-1, -2 62-1, -2, -3 63-2, -3, -4, -5, -7 through -17, -20	61-1, -2, -3 62-1, -2, -3 63-7, -13, -20	61-1, -2, -3 62-1, -2, -3 63-7, -13, -20
80% FI (3125-371)	none ^a	61-1 62-2	61-1, -2, -3 62-3 63-2, -3, -4, -7, -12, - 14 through -20	61-1, -2, -3 62-2, -3 63-2, -3, -4, -7 -12, -14, -16, -20

^a No data were required because the product was not registered at this time.

OPPTS 830 Series Guideline Conversion	
1982 Guideline	830 Guideline
61-1	830.1550
61-2	830.1600/1620/1650
61-3	830.1670
62-1	830.1700
62-2	830.1750
62-3	830.1800
63-2	830.6302
63-3	830.6303
63-4	830.6304
63-5	830.7200
63-6	830.7220
63-7	830.7300
63-8	830.7840/7860
63-9	830.7950
63-10	830.7370

63-11	830.7550/7560/7570
63-12	830.7000
63-13	830.6313
63-14	830.6314
63-15	830.6315
63-16	830.6316
63-17	830.6317
63-18	830.7100
63-19	830.6319
63-20	830.6320
63-21	830.6321
UV/Visible Absorption	830.7050

The current status of the product chemistry data requirements for the Bayer Corporation trichlorfon MPs is presented in the attached data summary tables. Refer to these tables for a listing of the outstanding product chemistry data requirements.

CONCLUSIONS

Provided that the registrant submits the data required in the attached summary tables for the trichlorfon MPs, and either certifies that the suppliers of starting materials and the manufacturing processes for the trichlorfon technicals and manufacturing-use products have not changed since the last comprehensive product chemistry review or submits complete updated product chemistry data packages, HED has no objections to the reregistration of trichlorfon with respect to product chemistry data requirements.

AGENCY MEMORANDA CITED IN THIS DOCUMENT

CBRS No(s): 9849
DP Barcode: D177981
Subject: Reregistration of Trichlorfon. Registrant's Response to Product Chemistry Data Requirements.
From: W. Smith
To: L. Rossi
Dated: 9/29/92
MRID(s): 41535301 and 41535302

CBRS No(s): 12487, 12488, and 12488
DP Barcode(s): D194772, D194771, and D194770
Subject: Trichlorfon. Product Chemistry Data Requirements.
From: S. Knizner
To: B. Lowery
Dated: 1/31/94
MRID(s): 42835201 through 42835209

PRODUCT CHEMISTRY CITATIONS

Bibliographic citations include only MRIDs containing data which fulfill data requirements.

00147436 Krohn, J. (1983) Letter sent to Hagen dated Jul 14, 1983: Partition coefficient of trichlorfon and methamidophos: Registration in Egypt. Translation of Verteilungskoeffizienten von trichlorfon und methamidophos: Registrierung in Aegypten prepared by Bayer AG, Mobay report 85931. 1 p.

00148973 Slahck, S. (1985) Composition of Technical Trichlorfon: Report No. 88931. Unpublished study prepared by Mobay Chemical Corporation. 25 p.

00152133 Mobay Chemical Corp. (1985) Product Chemistry of Trichlorfon Technical: Dylox Technical. Unpublished compilation. 22 p.

00158290 Talbott, T. (1986) Maximum and Minimum Certified Limits for Dylox 80 Concentrate Formulation: Report No. 90973. Unpublished study prepared by Mobay Chemical Corp. 13 p.

00162307 Technology Services Group (1986) Product Chemistry Data for Technical Trichlorfon. Unpublished compilation. 101 p.

41535301 Sewekow, ?. (1988) Vapor Pressure of Trichlorfon Pure Active Ingredient: Lab Project Number: 100 128: 87267. Unpublished study prepared by Mobay Corp. 11 p.

41535302 Weber, ?. (1987) Vapor Pressure of Trichlorfon Pure Active Ingredient: Lab Project Number: 681 538: 94641. Unpublished study prepared by Corp., and Bayer Ag. 7 p.

42835201 Fontaine, L. (1993) Product Chemistry of Dipterex Technical: Supplemental: Lab Project Number: MCL0006A: MCL0006B: 605161. Unpublished study prepared by Miles Inc. 30 p.

42835202 Fontaine, L. (1993) Product Chemistry of Dipterex Technical: Supplemental: Lab Project Number: 88931: 88935: 93156. Unpublished study prepared by Miles Inc. 75 p.

42835203 Fontaine, L. (1993) Product Chemistry of Dipterex Technical: Supplemental: Lab Project Number: 90153: 90155: 91700. Unpublished study prepared by Miles Inc. 86 p.

42835204 Fontaine, L. (1993) Product Chemistry of Dylox 80 Concentrate: Supplemental: Lab Project Number: 605161: 501968: 501821. Unpublished study prepared by Miles Inc. 53 p.

42835205 Fontaine, L. (1993) Product Chemistry of Dylox 80 Concentrate: Supplemental: Lab Project Number: 88931: 90973: 93156. Unpublished study prepared by Miles Inc. 61 p.

42835206 Fontaine, L. (1993) Product Chemistry of Dylox 80 Concentrate: Supplemental: Lab Project Number: 99697: 103879: 105144. Unpublished study prepared by Miles Inc. 15 p.

42835207 Fontaine, L. (1993) Product Chemistry of Dylox Technical: Supplemental: Lab Project Number: ANR-00393: BR 1832: MCL0340. Unpublished study prepared by Miles Inc. 16 p.

42835208 Fontaine, L. (1993) Product Chemistry of Dylox Technical: Supplemental: Lab Project Number: 105136: 105141: ANR-00493. Unpublished study prepared by Miles Inc. 55 p.

42835209 Fontaine, L. (1993) Product Chemistry of Dylox Technical: Supplemental: Lab Project Number: 86166: 90153:

90155. Unpublished study prepared by Miles Inc. 79 p.

44024701 Fontaine, L. (1996) Product Chemistry of Dipterex Technical: Supplemental: Lab Project Number: ANR-00496/ANR-00596. Unpublished study prepared by Bayer Corporation. 10 p.

44024702 Fontaine, L. (1996) Product Chemistry of Dipterex Technical: Supplemental: Lab Project Number: 93059. Unpublished study prepared by Bayer Corporation. 11 p.

44024703 Fontaine, L. (1996) Product Chemistry of Dipterex Technical. Lab Project Number 107211. Unpublished study prepared by Bayer Corporation. 10 p.

44024704 Fontaine, L. (1996) Product Chemistry of Dylox Technical: Supplemental: Lab Project Number: ANR-00296/ANR-00396. Unpublished study prepared by Bayer Corporation. 8 p.

44024705 Fontaine, L. (1996) Product Chemistry of Dylox Technical: Supplemental: Lab Project Number: ANR-00696. Unpublished study prepared by Bayer Corporation. 7 p.

44024706 Fontaine, L. (1996) Product Chemistry of Dylox Technical. Lab Project Number: 107218 & 107236. Unpublished study prepared by Bayer Corporation. 25 p.

Case No. 0104
Chemical No. 057901

Case Name: Trichlorfon

Registrant: Bayer Corp.

Product(s): 98% T (EPA Reg. No. 3125-9) and 98% T (EPA Reg. No. 11556-30, canceled)

No data have been submitted for the 98% T (EPA Reg. No. 11556-30); however data submitted for EPA Reg. No. 3125-9 may be used to satisfy product chemistry data requirements for EPA Reg. No. 11556-30. An individual CSF is required for each product.

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? ^a	MRID Number ^b
830.1550	Product Identity and Composition	N ^c	00152133 <u>42835201</u> 44024701*
830.1600 830.1620 830.1650	Starting Materials and Manufacturing Process	Y	00152133 <u>42835201</u> 44024701*
830.1670	Discussion of Formation of Impurities	Y	<u>42835201</u> 44024701*
830.1700	Preliminary Analysis	Y	00148973 <u>42835202</u> 44024702*
830.1750	Certified Limits	N ^d	00152133 <u>42835202</u>
830.1800	Enforcement Analytical Method	N ^e	00148973 <u>42835202</u>
830.6302	Color	Y	00152133
830.6303	Physical State	Y	00152133
830.6304	Odor	Y	00152133
830.6313	Stability	N ^g	00152133 <u>42835203</u> 44024703*
830.6314	Oxidation/Reduction	Y	00152133
830.6315	Flammability	N/A ^f	
830.6316	Explosibility	Y	00152133
830.6317	Storage Stability	Y	00152133
830.6319	Miscibility	N/A ^f	
830.6320	Corrosion Characteristics	Y	00152133 <u>42835203</u>
830.7000	pH	Y	00152133
830.7050	UV/Visible Absorption	N	no data submitted
830.7100	Viscosity	N/A ^f	
830.7200	Melting Point/Melting Range	Y	00152133
830.7220	Boiling Point/Boiling Range	N/A ^f	
830.7300	Density/Relative Density/Bulk Density	Y	00152133 <u>42835203</u>
830.7370	Dissociation Constant in Water	Y	00152133
830.7550 830.7560 830.7570	Partition Coefficient (Octanol/Water)	Y	00147436
830.7840 830.7860	Solubility	Y	00152133

830.7950	Vapor Pressure	Y	00152133 41535301 41535302
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^a Y = Yes; N = No; N/A = Not Applicable.

^b**Bolded** citations were reviewed in the Trichlorfon Reregistration Standard Update dated 5/15/90; underlined citations were reviewed under D194772, D194771, and D194770, dated 1/31/94, by S. Knizner; * citations reviewed in this review; the remaining citations were reviewed under D177981, dated 9/29/92, by W. Smith.

^c These data do not fully satisfy the requirements of 40 CFR § 158.155 (Guideline Reference No. 860.1550) regarding product identity because the registrant must submit upper certified limits for the impurities >0.1%.

^dThese data do not fully satisfy the requirements of 40 CFR §158.175 (GLN 830.1750) regarding certification of limits because the registrant must explain in more detail how the certified limits for the impurities, which greatly exceed the concentrations found in preliminary analysis, were established, or propose new certified limits for impurities which more closely reflect the results of preliminary analysis. An individual CSF is required for each of the 98% Ts.

^eThese data do not fully satisfy the requirements of 40 CFR §158.180 (GLN 830.1800) regarding enforcement analytical methods because complete validation data including precision and accuracy data must be submitted for all impurities for which certified limits have been proposed.

^fNot applicable because the TGAI/MP is a solid.

^gThese data do not fully satisfy the requirements of 40 CFR §158.190 (GLN 830.6313) because the stability of the TGAI upon exposure to metal ions is required.

Case No. 0104
Chemical No. 057901

Case Name: Trichlorfon
Registrant: Bayer Corporation, Agriculture Division
Product(s): 97% T (EPA Reg. No. 3125-404 canceled)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? ^a	MRID Number ^b
830.1550	Product Identity and Composition	Y	<u>42835207</u>
830.1600	Starting Materials and Manufacturing Process	Y	44024704*
830.1620			
830.1650			
830.1670		Y	<u>42835207</u> 44024704*
830.1700	Preliminary Analysis	Y	<u>42835208</u>
830.1750	Certified Limits	N ^d	<u>42835208</u>
830.1800	Enforcement Analytical Method	N ^e	<u>42835208</u>
830.6302	Color	Y	<u>42835209</u>
830.6303	Physical State	Y	<u>42835209</u>
830.6304	Odor	Y	<u>42835209</u>
830.6313	Stability	N	<u>42835209</u> 44024706*
830.6314	Oxidation/Reduction	N	no data submitted
830.6315	Flammability	N/A ^f	
830.6316	Explosibility	Y	44024706
830.6317	Storage Stability	N	no data submitted
830.6319	Miscibility	N/A ^f	
830.6320	Corrosion Characteristics	Y	<u>42835209</u>
830.7000	pH	Y	<u>42835209</u>
830.7050	UV/Visible Absorption	N	no data submitted
830.7100	Viscosity	N/A ^f	
830.7200	Melting Point/Melting Range	Y	<u>42835209</u>
830.7220	Boiling Point/Boiling Range	N/A	
830.7300	Density/Relative Density/Bulk Density	N	44024706
830.7370	Dissociation Constant in Water	Y	00162307
830.7550	Partition Coefficient (Octanol/Water)	Y	00162307 <u>42835209</u>
830.7560			
830.7570			
830.7840	Solubility	Y	00162307 <u>42835209</u>
830.7860			
830.7950	Vapor Pressure	Y	00162307 <u>42835209</u>

^a Y = Yes; N = No; N/A = Not Applicable. Although Miles (now Bayer) has indicated that current data submissions are supplemental to Kaw Valley data for EPA Reg. No. 44215-129 reviewed in the Trichlorfon Update, the recent submissions indicated that the composition of the product has changed since the Update. Bayer has certified that the manufacturing process has not changed since the transfer of the product. They explain that the differences in the preliminary analysis are due to differences in the analytical method used. However, Bayer has not certified that the starting materials and the manufacturing process and location have not changed since the transfer of the

product. This certification is still needed or a whole new set of Product chemistry data must be submitted. (In which case, the only data previously submitted for the Kaw Valley 97% T which can be transferred to the Miles product are PAI data.)

^b **Bolded** citations were reviewed in the Trichlorfon Reregistration Standard Update dated 5/15/90; underlined citations were reviewed under D194772, D194771, and D194770, dated 1/31/94, by S. Knizner. and reconsidered under D218322, dated 9/25/95, S. Hummel; *citations reviewed in this review.

^c These data do not fully satisfy the requirements of 40 CFR §158.167 (GLN 830.1670) regarding discussion of formation of impurities because the origin of one impurity listed on the CSF must be submitted.

^d These data do not fully satisfy the requirements of 40 CFR §158.175 (GLN 830.1750) regarding certification of limits because upper certified limits must be provided for four impurities which are present at >0.1% in the product. The registrant should note that impurities associated with the active ingredient are considered toxicologically significant unless the registrant proves otherwise.

^e These data do not fully satisfy the requirements of 40 CFR §158.180 (GLN 830.1800) regarding enforcement analytical methods because accuracy data (demonstrating adequate recoveries of fortified samples) must be submitted for the analytical method used for the determination of trichlorfon. In addition, precision data are required for two impurities listed on the CSF with a proposed upper certified limit, and accuracy data are required for four impurities listed on the CSF with proposed upper certified limits. In addition, enforcement analytical methods and supporting validation data must be submitted for three impurities for which upper certified limits are now required.

^f Requirement is not applicable because product is a solid at room temperature..

Case No. 0104
Chemical No. 057901

Case Name: Trichlorfon
Registrant: Bayer Corporation, Agriculture Division
Product(s): 80% FI (EPA Reg. No. 3125-371)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? ^a	MRID Number ^b
830.1550	Product Identity and Composition	Y	00158290 <u>42835204</u>
830.1600	Starting Materials and Manufacturing Process	Y	<u>42835204</u>
830.1620			
830.1650			
830.1670	Discussion of Formation of Impurities	Y	<u>42835204</u>
830.1700	Preliminary Analysis	N/A ^c	
830.1750	Certified Limits	Y	00158290 <u>42835205</u>
830.1800	Enforcement Analytical Method	Y	<u>42835205</u>
830.6302	Color	Y	<u>42835206</u>
830.6303	Physical State	Y	<u>42835206</u>
830.6304	Odor	Y	<u>42835206</u>
830.6313	Stability	N/A ^c	
830.6314	Oxidation/Reduction	Y	<u>42835206</u>
830.6315	Flammability	N/A ^d	
830.6316	Explosibility	Y	<u>42835206</u>
830.6317	Storage Stability	Y	43139501*
830.6319	Miscibility	N/A ^d	
830.6320	Corrosion Characteristics	Y	43139501*
830.7000	pH	Y	<u>42835206</u>
830.7050	UV/Visible Absorption	N/A ^c	
830.7100	Viscosity	N/A ^d	
830.7200	Melting Point/Melting Range	N/A ^c	
830.7220	Boiling Point/Boiling Range	N/A ^c	
830.7300	Density/Relative Density/Bulk Density	Y	<u>42835206</u>
830.7370	Dissociation Constant in Water	N/A ^c	
830.7550	Partition Coefficient (Octanol/Water)	N/A ^c	
830.7560			
830.7570			
830.7840	Solubility	N/A ^c	
830.7860			
830.7950	Vapor Pressure	N/A ^c	

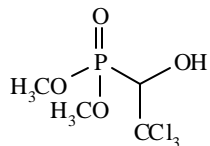
^a Y = Yes; N = No; N/A = Not Applicable.

^b **Bolded** citations were reviewed in the Trichlorfon Reregistration Standard Update Addendum dated 7/23/90; underlined citations were reviewed under D194772, D194771, and D194770, dated 1/31/94, by S. Knizner, and the review updated by D218322, dated 9/25/95, S. Hummel. MRIDs marked with an "*" were reviewed under D216944, dated 8/2/95, K. Dockter.

^c These data requirements will be satisfied by the technical source product (TGAI).

^d Not applicable because the MP is a solid.

TRICHLORFON



REREGISTRATION ELIGIBILITY DOCUMENT

RESIDUE CHEMISTRY CONSIDERATIONS

PC Code: 057901; Case No. 0104

(DP Barcode D257225)

INTRODUCTION

Trichlorfon [dimethyl (2,2,2-trichloro-1-hydroxyethyl) phosphonate] is a selective chlorinated organophosphorus insecticide currently registered (for import uses only) for the control of cattle grub and cattle lice as a direct application to beef and dairy (younger than breeding age) cattle using liquid ready-to-use (RTU) formulations (8% active ingredient).

REGULATORY BACKGROUND

Trichlorfon was originally referred and entered in the Rebuttable Presumption Against Registration (RPAR, now referred to as Special Review) process because scientific studies suggested that trichlorfon might be oncogenic, teratogenic, fetotoxic, and mutagenic (FR Vol. 43, No. 77, 4/20/78). In 1984 the Agency evaluated the available data on trichlorfon and concluded that the existing evidence did not support the issuance of an RPAR for trichlorfon because the existing database was inadequate for valid risk assessment.

The Trichlorfon Reregistration Standard was issued 7/18/83. The Standard identified numerous residue chemistry data deficiencies including plant and animal metabolism, residue analytical methods, storage stability data, and magnitude of the residue in plants and in animals.

The Trichlorfon Reregistration Standard Update was issued 5/15/90. The Update evaluated all residue chemistry data submitted since the Standard and reiterated the remaining outstanding deficiencies. The Update additionally required field trial and processing data depicting residues of DDVP, a potential metabolite of trichlorfon which has been classified by the Agency as a carcinogen.

Since issuance of the Update, Bayer Corp., one of the basic producers of trichlorfon has indicated that it does not intend to support the crop food/feed uses of trichlorfon on its product labels. A voluntary request for amendments to delete uses on the following food/feed crops was published in the Federal Register (FR Vol. 57, No. 214, 11/4/92): alfalfa, bananas, barley, beets (table), birdsfoot trefoil, blueberries, clover, corn (field, pop, sweet), cotton, pumpkins, soybeans, tobacco, tomatoes, and wheat. Bayer Corp. had also indicated that trichlorfon uses in poultry packing plants and food areas of food-handling establishments will not be supported. Although the remaining trichlorfon registrants have not deleted the food/feed uses from their labels, the Agency believes that these crop food/feed uses will not be supported because no residue chemistry data have been submitted since the Update.

Bayer Corp. has expressed its intention to maintain the dermal, pour-on use of trichlorfon on beef and dairy (younger than breeding age) cattle for import purposes only (see letter dated 1/29/92 from T. Waggoner of Miles to R. Forrest, RD). Two insect pests (cattle grub and cattle lice) are controlled by dermal application of trichlorfon to cattle. Trichlorfon acts systemically to control the cattle grub (a parasite), by circulating through the animal from the dermal application site (animal's backline) to the area where the controlled organisms are located (animal's gullet and spinal cord) before taking effect. This is opposed to non-systemic pesticidal action in which the pesticide does not have to circulate through the animal in order to control the target pest.

HED has no objections to the reregistration of trichlorfon, provided all uses with food/feed ramifications, with the exception of the dermal pour-on application to beef and dairy (younger than breeding age) cattle for import purposes only, are canceled. HED would require a cattle dermal metabolism study and a magnitude of the residue study reflecting dermal application. These studies are under review now. (T. Morton, D244279). A residue analytical method as well as magnitude of residue data from dermal applications may be required if additional residues of concern other than trichlorfon *per se* are determined.

Tolerances with no U.S. registration for residues of trichlorfon in/on food and feed items are currently expressed in terms of trichlorfon [dimethyl (2,2,2-trichloro-1-hydroxyethyl) phosphonate] *per se* [40 CFR §180.198]. These tolerances are 0.1 (N) ppm for cattle meat, meat-by-products, and fat.

GLN 860.1200: Directions for Use

A REFs search conducted 6/7/99 and a LUIS Report dated 2/19/99 identified 13 trichlorfon end-use products (EPs). All of these EPs (see Table A) were examined to determine whether labels have been amended to delete crop food/feed uses.

Some of the EPs listed in Table A carry use directions for surface spray or broadcast treatment in farm buildings (including dairy barns) and food-handling establishments; however, these uses are classified as non-food uses because adequate restrictions exist regarding the potential for residue transfer. When trichlorfon is applied in farm buildings, animals are removed before treatment; there are label restrictions against contamination of milk, milk-handling equipment, feed, drinking water, litter, feed troughs, and

portions of buildings where animals can lick the treated surface.

The Neguvon label states “Do not treat cattle within 21 days of slaughter”. The pre-slaughter interval stated on the Neguvon label (EPA Reg. No. 11556-32) must be amended to specify a preslaughter interval of 1-3 days.

Table A. Currently Registered Trichlorfon End-Use Products (REFS search dated 6/7/99).

Registrant	EPA Reg. No.	% AI and Formulation	Label Date	Food/Feed Uses?
Prentiss Inc.	655-790	5% G	11/97	No
	655-791	5% G	11/97	No
Bayer Corporation	3125-184	80% WP	11/93	No
	3125-400	6.2% G	3/94	No
	3125-406	6.2% G	9/90	No
	3125-449	80% SP	6/96	No
	3125-507	6.2% G	11/97	No
The Andersons	8660-71	6.2% G	10/92	No
The Andersons Lawn & Fertilizer Division	9198-110	6.2% G	7/92	No
Drexel Chemical Co.	19713-220	5% G	1/96	No
Howard Johnson's Enterprises, Inc.	32802-29	6.2% G	8/95	No
Arkansas Bait & Ornamental Fish Growers Association	AR98000300	80% WP	4/98	No
California Aquaculture Assoc.	CA98001400	80% WP	7/98	No

GLN 860.1300 Nature of the Residue - Plants, Animals:

The nature of the residue is not adequately understood (T. Morton, D244279). Additional data is required pertaining to the nature of the residue in animals (dermal treatment). Once the nature of the residue is adequately understood, the results will be presented to the HED Metabolism Assessment Review Committee for determination of the trichlorfon residues of concern in cattle.

GLN 860.1340 Residue Analytical Method:

Adequate methodology is available for enforcement of tolerances with no U.S. registration for residues of trichlorfon *per se* in/on animal commodities. A GC/ECD method for trichlorfon, chloral hydrate, and trichloroethanol is included in PAM, Vol. II as Method B. The residue is extracted from animal tissues with acetonitrile then Skellysolve B, partitioned with n-heptane (to remove fats and oils), and extraction made with ether. Following evaporation, the residue is dissolved in benzene and an aliquot is injected into a gas chromatograph with electron capture detection. Sensitivity is 0.1 ppm. A residue analytical method may be required if additional residues of concern are determined.

GLN 860.1380 Storage Stability Data:

Storage stability in tissues of cattle is adequate (T. Morton, D244279). Trichlorfon residues are stable in cattle tissues for 3 months under frozen conditions (-80° C). Dichlorvos residues are stable in cattle muscle and fat for 3 months under frozen conditions (-80° C). Dichlorvos recoveries in fortified liver and kidney samples were significantly lower than those from the concurrent recovery samples. Results from a separate short time room temperature storage stability study showed dichlorvos undergoes degradation in a short time (<2 hours) between fortification and extracting. Average recoveries for dichlorvos in liver and kidney samples immediately extracted were 55 % and 91 % respectively. Samples taken for dichlorvos analysis must be analyzed immediately to prevent loss of the residue at room temperature. Dichlorvos in cattle liver and kidney may remain relatively stable under frozen conditions (-80° C).

GLN 860.1480 Meat/milk/poultry/eggs:

Residues of trichlorfon and dichlorvos were < 0.05 ppm in livestock commodities at pre-slaughter intervals of 1, 3, and 7 days (T. Morton, D244279). The Neguvon label states “Do not treat cattle within 21 days of slaughter”. The pre-slaughter interval stated on the Neguvon label (EPA Reg. No. 11556-32) must be amended to specify a preslaughter interval of 1-3 days.

Additional residue data may be required if additional residues of concern are identified by the HED Metabolism Assessment Review Committee.

Table B. Residue Chemistry Science Assessments for Reregistration of Trichlorfon.

<u>GLN: Data Requirements</u>	<u>Tolerances, ppm [40 CFR]</u>	<u>Must Additional Data Be Submitted?</u>	<u>References¹</u>
<u>860.1200: Directions for Use</u>	<u>N/A = Not Applicable</u>	<u>Yes^a</u>	
<u>860.1300: Plant Metabolism</u>	<u>N/A</u>	<u>N/A</u>	
<u>860.1300: Animal Metabolism</u>	<u>N/A</u>	<u>Yes^b</u>	44500701 44500702
<u>860.1340: Residue Analytical Methods</u>	<u>N/A</u>	<u>No^c</u>	44500704
<u>860.1380: Storage Stability</u>	<u>N/A</u>	<u>No^c</u>	44781401
<u>860.1400: Water, fish, and irrigated crops</u>	<u>N/A</u>	<u>N/A</u>	
<u>860.1460: Food handling</u>	<u>N/A</u>	<u>N/A</u>	
<u>860.1480: Meat, milk, poultry, and eggs</u>	<u>§180.198</u>	<u>No^c</u>	44500703
<u>860.1500: Crop field trials</u>	<u>N/A</u>	<u>N/A</u>	
<u>860.1520: Processed food/feed</u>	<u>N/A</u>	<u>N/A</u>	
<u>860.1850: Confined accumulation in rotational crops</u>	<u>N/A</u>	<u>N/A</u>	

<u>GLN: Data Requirements</u>	<u>Tolerances, ppm [40 CFR]</u>	<u>Must Additional Data Be Submitted?</u>	<u>References¹</u>
<u>860.1900: Field accumulation in rotational crops</u>	<u>N/A</u>	<u>N/A</u>	

^a The pre-slaughter interval stated on the Neguvon label (EPA Reg. No. 11556-32) must be amended to specify a preslaughter interval of 1-3 days.

^b Additional data required.

^c Additional data may be required if additional residues of concern are identified by the HED Metabolism Assessment Review Committee.

TOLERANCE REASSESSMENT SUMMARY

The tolerances listed in [40 CFR §180.198] are for residues of trichlorfon in/on animal products. A footnote must be added to the tolerance listing in [40 CFR §180.198] that states “There are no United States registration for cattle commodities as of 6/24/99.” Reassessment of tolerances will be completed at this time using reassessed tolerances.

Table C. Tolerance Reassessment Summary for Trichlorfon.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comments
Tolerances listed under 40 CFR §180.198			
Cattle, fat	0.1 (N)	0.5	
Cattle, mbyp	0.1 (N)	0.1	
Cattle, meat	0.1 (N)	0.2	

CODEX HARMONIZATION

There are no Codex Maximum Residue Levels for residues of trichlorfon. Thus harmonization is not required.

DIETARY EXPOSURE REASSESSMENT

Sufficient residue data are available to estimate that the existing tolerances with no U.S. registration for cattle, meat and cattle, fat are likely to require modification. For this document, the dietary exposure estimate will include residues of trichlorfon *per se* and dichlorvos. Once the residues of concern are determined by the HED metabolism committee the dietary exposure may have to be reassessed. Reassessed tolerances in addition to % beef/veal imported into the U.S. will be used in the dietary exposure analysis.

MASTER RECORD IDENTIFICATION NUMBERS

[Some of these references may have been used in the establishment of the trichlorfon tolerances. As a result of voluntary cancellation of all food/feed uses of trichlorfon, these references were not used in this document.]

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